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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,429	02/13/2002	Rosa Martani	3-31105A	8742

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,429	MARTANI, ROSA	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the appeal brief filed on 10/24/05, PROSECUTION IS HEREBY REOPENED. New ground of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid. A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

Double Patenting

Non-statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6,083,531 ('531), in view of Schultz et al. US 6,194,395 or Pharmaceutical Dosage Forms and Drug Delivery Systems (Ansel et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because '531 claims a solid pharmaceutical dosage form comprising active substance, filler, binding agent, and usual auxiliaries. The solid dosage form is disintegrates in the mouth within 15 seconds (claim 1). Filler and binder are found in claims 2. The density of the dosage form is found in claims 3 and 4. The amounts of the ingredients are found in claims 7 and 8. Lubricant is found in claim 12. The '531 patent does not claim the claimed disintegrant, including polymethylmethacrylate (claim 13), however, '531 claimed binding agent and usual auxiliaries (claim 1). Binding agent includes starch, cellulose materials, and polyvinylpyrrolidones (PVP) (claim 2). Schultz teaches the use of binder such as croscarmellose sodium, PVP, and crospovidone in oral solid dosage form, such as fast dissolving wafers (column 5, lines 37-78; and column 6, lines 3-5). Ansel et al. teach disintegrating agent includes croscarmellose, starch, PVP, and crospovidone (cross linked polyvinylpyrrolidone). Thus, those of ordinary skill would expect a similar quick dissolve solid dosage form having the claimed disintegration time from the use of the instant invention given the claims of the '531, in view of Schultz et al. or Ansel et al.,

because Schultz teaches the equivalency of crocarmellose sodium and PVP and cropovidone, because Schultz teaches corspovidone can be used as a binder, because Ansel et al. teach the equivalency of PVP and cropovidone, as they both can be used as a disintegrant, and because the '531 teaches the use of PVP as well as other binding agents that can also be used as a disintegrant. There are no unusual and/or unexpected results, which would rebut prima facie obviousness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679.

Humbert-Droz teaches process for preparing fast disintegrating oral dosage form discloses in pages 5-6. It appears that Humbert-Droz is silent as to the teaching of compacting a suitable amount of the prepared powder or granulate as claimed in step (c). However, no unexpected and/or unusual results are seen in the particular step, since the prior art obtains the same result desire by the applicant, e.g., fast disintegrating oral dosage. Although, Humbert-Droz does not teach compacting the prepared powder or granulate, the extra step does not impart patentability over the applied prior art. Applicant's desire to produce rapidly dissolving dosage form,

Humbert-Droz produces rapidly dissolving oral dosage form. Thus, it would have been prima facie obvious for one of ordinary skill in the art to, by routine experimentation modify the process of Humbert-Droz to obtain the claimed composition with or without compressing step, because Humbert-Droz teaches tablet obtain by compression is well known in pharmaceutical art (page 1, 1st paragraph), and because Humbert-Droz teaches a rapidly dissolving oral dosage form having the same density and the same disintegrating time. With regarding to the composition claims, it is the position of the examiner that one of ordinary skill in the art would have been motivated to modify Humbert-Droz's composition to obtain the claimed invention because Humbert-Droz teaches a rapidly dissolving oral dosage form having the claimed density of 200-1000 mg/ml, and disintegrating time of within 15 seconds (pages 2-5).

Claims 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679, in view of Schultz et al. US 6,194,395.

Humbert-Droz is relied upon for the reasons above. Humbert-Droz does not teach the claimed disintegrant. However, Humbert-Droz teaches the use of binder includes starch, cellulose materials, and polyvinylpyrrolidones (PVP) (claims 4-7). Schultz teaches the use of binder such as croscarmellose sodium, PVP, and crospovidone in oral solid dosage form, such as fast dissolving wafers (column 5, lines 37-78; and column 6, lines 3-5). Thus, it would have been obvious to one of ordinary skill in the art to modify the fast disintegrating oral dosage form of Humbert-Droz using croscarmellose sodium, PVP, or crospovidone as a binder in view of the teaching of

Schultz to obtain the claimed invention, because Schultz teaches the equivalency of crocarmellose sodium and PVP and cropovidone, because Schultz teaches corspovidone can be used as a binder, because Schultz teaches the use of the well known disintegrants as a binder, and because Humbert-Droz teaches the use of binder such as starch, PVP in a fast disintegrating oral dosage form.

Claims 13-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humbert-Droz et al. WO 97/38679, in view of the Pharmaceutical Dosage Forms and Drug Delivery Systems (Ansel et al.).

Humbert-Droz is relied upon for the reasons above. Humbert-Droz does not teach the claimed disintegrant. However, Humbert-Droz teaches the use of binder includes starch, cellulose materials, and polyvinylpyrrolidones (PVP) (claims 4-7). Ansel et al. teach disintegrating agent includes croscarmellose, starch, PVP, and crospovidone (cross linked polyvinylpyrrolidone). Thus, it would have been obvious to one of ordinary skill in the art to modify the fast disintegrating oral dosage form of Humbert-Droz using the disintegrating agent in view of the teaching of Ansel to obtain the claimed invention, because Ansel teaches the equivalency of PVP and cropovidone, as they both can be used as a disintegrant, and because Humbert-Droz teaches the use of PVP as well as other binding agents that can also be used as a disintegrant.

Response to Arguments

Applicant argues that it not proper to conclude that two different processes are similar merely because there are similarities in the disintegrating properties of the end products. However, it would have been obvious to one of ordinary skill in the art to modify the process of Humbert-Droz with or without compression force depends in the desirability of the disintegration rate, as well as the density, especially when Humbert-Droz recognizes that compression tablet is well known in pharmaceutical art. Furthermore, Humbert-Droz also teaches tablet such as OraSolv® is made my compression and having disintegrating time of 15-60 seconds, which is within the claimed range (see claim 15).

Applicant argues that the present process dose not have the initial step of dissolving or suspending all the ingredients in a solvent. Contrary to the applicant's argument, the use of the transitional phrase "comprising" does not exclude other steps in the prior arts.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER
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